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PHA 3300.1 (01449/1)
PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Rory F. Finn

Art Unit 1632

Serial No. 10/718,340

Filed November 20, 2003

Confirmation No. 3646

For N-TERMINALLY MONOPEGYLATED HUMAN GROWTH HORMONE
CONJUGATES AND PROCESS FOR THEIR PREPARATION

August 5, 2005

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SIR:

INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance
* with the duty of disclosure set forth in 37 C.F.R. 1.56, applicant submits the attached
PTO/SB/08A for consideration by the Patent and Trademark Office in the above-
entitled application and to be made of record therein.

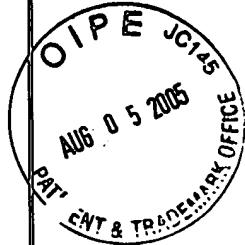
* Applicant submits herewith copies of the foreign patent documents and literature
references.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R.
§1.97(b) in that applicants believe that it is being filed prior to the mailing date of the
first Office action on the merits. Accordingly, neither a statement nor fee under 37
C.F.R. §1.97(c) or (d) is required.

Respectfully submitted,

Edward J. Hejek, Reg. No. 31,525
SENNIGER POWERS
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
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PTO/SB/08A

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT*Complete if Known*

Application Number	10/718,340
Filing Date	November 20, 2003
Confirmation Number	3646
First Named Inventor	Rory F. Finn
Group Art Unit	1632
Examiner Name	Maury A. Audet

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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	1	4,002,531		Royer	01-11-1977
	2	4,179,337		Davis et al	12-18-1979
	3	4,658,021		Goeddel et al	04-14-1987
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	5	5,183,660		Ikeda et al	02-02-1993
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	7	5,633,352		Dalb.oslashet al	05-27-1997
	8	5,643,575		Martinez et al	07-01-1997
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	12	5,932,462		Harris et al	08-03-1999
	13	6,113,906		Greenwald et al	09/05/2000

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

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Sheet	2	of	4	Attorney Docket No.	PHA 3300.1 (01449/1)

FOREIGN PATENT DOCUMENTS

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		Office	Number ⁴	Kind Code ² (if known)			
14	EP	0 154 316	A2	Takeda Chemical Industries, Ltd.	09-11-1985		
15	EP	0 335 423	A2	Kyowa Hakko Kogyo	10-04-1989		
16	EP	0 401 384	A1	Kirin-Amgen Inc.	12-12-1990		
17	EP	0 458 064	A2	American Cyanamid Company	11-27-1991		
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19	CN	1316436	A	Zho Jian	10-10-2001	✓	
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21	CN	1477126	A	Jinsai Pharmaceuticals Ltd.	02-25-2004	✓	
22	WO	90/05534	A1	Genentech, Inc.	05-31-1990		
23	WO	93/00109	A1	Genentech, Inc.	01-07-1993		
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26	WO	97/11178	A1	Genentech, Inc.	03-27-1997		
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	30	WO	03/044056	A2	Pharmacia Corp.	05-30-2003	
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OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	31	ABUCHOWSKI, A. et al, "Soluble Polymer - Enzyme Adducts", Enzymes as Drugs, (1981), pp. 367-383	
	32	CHAMOW, S.M. et al, "Modification of CD4 Immunoadhesin with Monomethoxypoly(ethyleneglycol) Aldehyde via Reductive Alkylation", Bioconjugate Chem, (1994), pp. 133-140, Vol. 5	
	33	CLARK, R. et al, "Long-acting Growth Hormones Produced by Conjugation with Polyethylene Glycol", Journal of Biological Chemistry, (1996), pp. 21969-21977, Vol. 271:36	
	34	HARRIS, J. M. et al, "Pegylation: A Novel Process for Modifying Pharmacokinetics", Drug Delivery Systems, (2001), pp. 539-551, Vol. 40:7	
	35	HUTCHINS, R.O. et al., "Cyanoborohydride, Utility and Applications in Organic Synthesis. A Review", Organic Preparations and Procedures Int., (1979), pp. 201-246, Vol. 11:5	
	36	KATRE, N.V., "The Conjugation of Proteins with Polyethylene Glycol and Other Polymers; Altering Properties of Proteins to Enhance their Therapeutic Potential", Advanced Drug Deliver Reviews, (1993), pp. 91-114, Vol. 10	
	37	KINSTLER, O.B. et al., "Characterization and Stability of N-terminally PEGylated rhG-CSF", Pharmaceutical Research, (1996), pp. 996-1002, Vol. 13:7	
	38	KNAUF, M.J. et al, "Relationship of Effective Molecular Size to Systemic Clearance in Rats of Recombinant Interleukin-2 Chemically Modified with Water-soluble Polymers", The Journal Biological Chemistry, (1988), pp. 15064-15070, Vol. 263:29	
	39	KODERA, Y. et al., "Stabilization of L-Asparaginase Modified with Comb-Shaped Poly(ethylene glycol) Derivatives, in Vivo and in Vitro", Bioconjugate Chemistry, (1994), pp. 283-286, Vol. 5:4	
	40	MEANS, G.E., "Reductive Alkylation of Proteins", Journal of Protein Chemistry, (1984), pp. 121-130, Vol. 3:1	

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41	OLSON, K. et al, "Preparation and Characterization of PEGylated Human Growth Hormone and Human Growth Hormone Mutants", Polymer Preprints, (1997), pp. 568-569, Vol. 38:1
42	ROBERTS, M.J. et al, "Chemistry for peptide and protein PEGylation", Advanced Drug Delivery Reviews, (2002), pp. 459-476, Vol. 54
43	WETZEL, R. et al., "A General Method for Highly Selective Cross-Linking of Unprotected Polypeptides via pH-Controlled Modification of N-Terminal α -amino Groups", Bioconjugate Chem., (1990), pp. 114-122, Vol. 1:2

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